Message

From: Faeth, Lisa [Faeth.Lisa@epa.gov]
Sent: 4/25/2019 3:08:54 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Washington State Gives Regulators Power to Ban Chemicals

By Paul Shukovsky

Posted April 24, 2019, 6:30 PM

Washington state regulators will be able to review a broad range of toxic chemicals with an eye to banning their use under a bill passed by the state legislature and heading for the governor's signature.

White House Eases Challenges to Data Used in Rulemaking (1)

By Cheryl Bolen

Posted April 24, 2019, 12:05 PMUpdated April 24, 2019, 4:45 PM

Flaws in government data or analysis used to support federal rulemaking will be easier to challenge under new guidance released today by the White House's Office of Management and Budget.

INSIDEEPA.COM ARTICLES

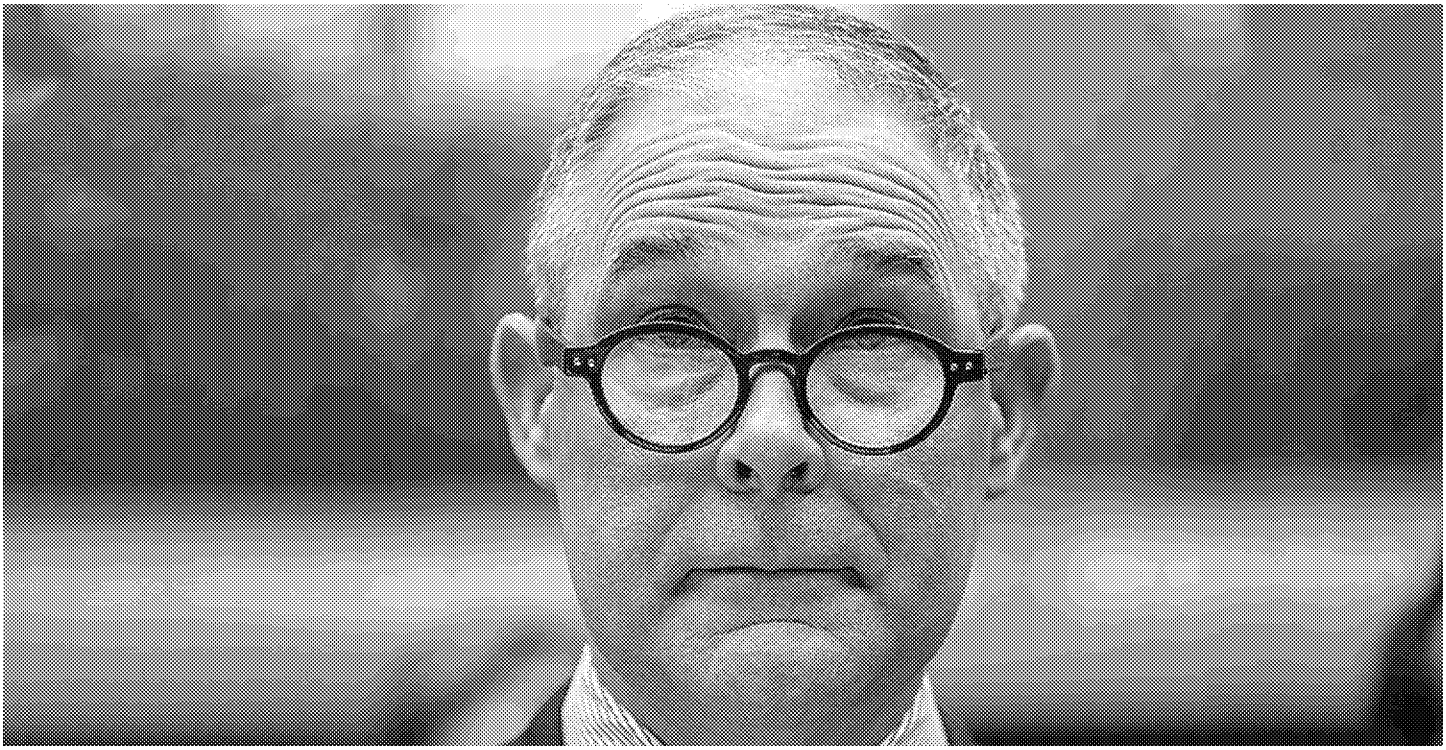
EPA Seeks To Update Cancer Risk Guide, Plans New Non-Cancer Guide

Administrator Andrew Wheeler is asking the agency's science advisors for advice on how to update EPA's guide for assessing chemicals' cancer risks, as well as for crafting new guidance for assessing non-cancer risks and for better communicating risks, suggesting an effort to extend the administration's deregulatory approach to its risk assessment practices.

GREENWIRE ARTICLES

Pruitt's lawyer sought billionaire's help for fund

Kevin Bogardus, E&E News reporter Published: Wednesday, April 24, 2019



Former EPA Administrator Scott Pruitt testifies during an April 2018 House hearing. Ken Cedeno/UPI/Newscom

When you're an embattled EPA administrator, it helps to have a well-connected lawyer.

Last year, former EPA chief Scott Pruitt's legal defense fund received a $50,000 contribution from Diane Hendricks, a billionaire businesswoman and Republican donor. That donation was sought by a friend of Hendricks, Cleta Mitchell, partner at Foley & Lardner LLP — and trustee of Pruitt's fund.

In a letter to E&E News, Karl Leo, an attorney representing Hendricks, said she was approached by Mitchell, who he said is a friend of hers, about donating to Pruitt's fund.

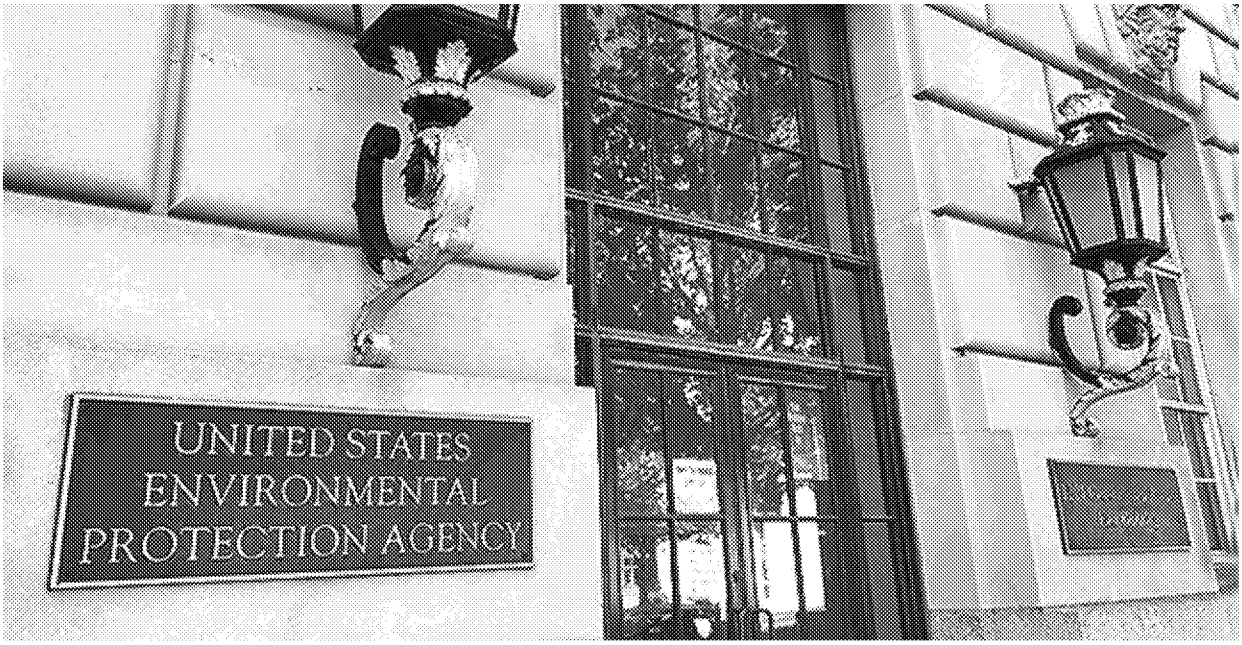
"Ms. Mitchell asked Ms. Hendricks to make the donation because Mr. Pruitt was being subjected to a variety of unfair legal charges and proceedings and he needed funds to defend himself against such charges while he served his country as the USEPA Administrator," said Leo, founder and president of Leo Law Firm LLC in Huntsville, Ala.

https://www.eenews.net/greenwire/2019/04/24/stories/1060211709

Safety board wants EPA to act on refinery chemical

Courtney Columbus, E&E News reporter

Published: Wednesday, April 24, 2019



EPA headquarters in Washington. Robin Bravender/File/E&E News

This story was updated at 2:10 p.m. EDT.

The Chemical Safety Board is calling on EPA to address hydrofluoric acid, a toxic chemical used by petroleum refineries.

In a letter to EPA Administrator Andrew Wheeler, CSB Interim Executive Authority Kristen Kulinowski urged EPA to review and update its 1993 study on the substance.

In the letter, Kulinowski calls for EPA to assess refineries' risk management plans and decide whether there are safer, commercially viable alternatives available.

"In the last four years, the CSB has investigated two refinery incidents where an explosion elevated the threat of a release of HF," she said in a statement.

CHEMICAL WATCH ARTICLES

Expert Focus: The new Australian Industrial Chemical Introduction Scheme

24 April 2019 / Australia, Personal care, Retail

Lucy Hartland and Sylvie Tso, of Spruson & Ferguson Lawyers in Sydney, discuss reforms to the regulation of industrial chemicals in Australia under AICIS, including a ban on the use of animal test data.

From 1 July 2020, the Australian Industrial Chemical Introduction Scheme (AICIS) for the regulation of industrial chemicals will come into force. Brought into effect by a suite of six pieces of legislation, the centrepiece of these is the Industrial Chemicals Act 2019.

AICIS replaces the National Industrial Chemicals Notification and Assessment Scheme (Nicnas) for the purpose of regulating the introduction – whether by manufacturing or through importation – of new industrial chemicals in Australia.

While some aspects of the existing regulatory system will not change, an important development is the move to a proportionate risk-based framework. This should see the regulatory burden for those seeking to introduce new industrial chemicals reduced, especially if those industrial chemicals have already been the subject of assessment by comparable overseas regulators. The new rules, which will set out the details of this, are currently the subject of consultation.

Although AICIS will only take effect on 1 July 2020, changes in anticipation are already underway, including in respect of 'polymers of low concern'.

Another amendment to the overall framework is a ban on the use of new animal test data for ingredients solely used in cosmetics. This reflects a global trend away from the use of animal test data in cosmetics.

This article highlights some of the changes that take effect on 1 July 2020.

Overview of AICIS

AICIS will regulate industrial chemicals, which include:

- a chemical element, a compound or complex of a chemical element, an unknown variable composition or biological substance (referred to in the Act as a UVCB substance), and a naturally occurring chemical, where any of these has an industrial use;
- a chemical released from an article, where the article has an industrial use; and
- any other chemical or substance prescribed by the rules that has an industrial use.

As can be seen from the above, the key element of an industrial chemical is that it has an "industrial use". Where the chemical is only used as a therapeutic good, food, and agricultural/veterinary chemical product (each of these is regulated by a separate legislative regime), it is not an industrial chemical.

Common industrial chemicals may include those used in:

- cosmetics, which encompass products such as makeup, soap, shampoo, deodorant, hair dye and other similar items;
- cleaning and other domestic products;
- various industries such as mining and metal extraction;
- fuel and oil;
- printing and photography;
- surface coatings;
- plastics; and
- engineering.

The central concern of AICIS is the introduction of new industrial chemicals in Australia. Industrial chemicals that are already listed on the Australian Inventory of Industrial Chemicals can be manufactured or imported by any person or entity that is registered as an 'introducer', provided that introduction complies with the terms of the listing.

Introducing new industrial chemicals

'A review by the Productivity Commission of the existing system of regulation of industrial chemicals considered that Nicnas was not sufficiently risk based'

A review by the Productivity Commission of the existing system of regulation considered that Nicnas was not sufficiently risk based, with criticism that there was undue focus on the assessment of low-risk new industrial chemicals, which could be subject to the same assessment procedures as those that were high-risk. Similarly, new industrial chemicals that had already been subject to assessment in other jurisdictions were still subject to this under Nicnas.

As set out in the explanatory memorandum to the bill introducing the Act, "[The Act] rebalances pre- and post-introduction regulatory controls for industrial chemical introductions so that there will be less emphasis on pre-introduction assessment of lower-risk new chemicals and a greater focus on post-introduction evaluation and monitoring."

To do this, AICIS will now provide for six categories of introduction of new industrial chemicals as follows:

- Listed introductions. These are for an industrial chemical that is listed on the inventory and where the introduction is within any terms of the listing. There are more than 40,000 chemicals on the inventory (currently under Nicnas but this will be transferred to AICIS by the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019). If an introducer seeks to introduce an industrial chemical that is listed on the inventory then one of the other five categories of introduction will be needed;
- Exempted introductions. These are for very low-risk industrial chemicals. The relevant risk is to human health and the environment posed by the introduction of the new industrial chemical. The rules will set the parameters for the kinds of introductions that can fall within this category;
- Reported introductions. These are for low-risk industrial chemicals and will require a pre-introduction report. The rules are expected to provide further guidance, and in particular to provide for the use of a risk assessment or evaluation undertaken by, or in association with, a trusted international body for chemicals. So that a new

industrial chemical that might otherwise be regarded as medium to high risk may utilise the same pathway as a low-risk industrial chemical;

- Assessed introductions. These are for medium- to high-risk industrial chemicals and will require an assessment certificate, which is obtained via the procedure set out in Part 3, Division 3 of the Act. Once there is an assessment certificate for an industrial chemical, it will be listed on the inventory after five years. However, applications can be made for early listing and industrial chemicals can be listed in certain other circumstances. Although a certificate will be issued for a chemical introduction based on an assessment of the information available at the time it is introduced, the Act allows for the reconsideration and review of the certificate. This allows the possibility of cancellation if the executive director is "not satisfied that the risks to human health or the environment from the introduction and use of the industrial chemical can be managed". It will also be possible for certificates to be refused on this basis;

- Commercial evaluation introductions. These are for testing the market viability of the industrial chemical before full introduction; and

- Exceptional circumstances introductions. These are for cases where there is ministerial authorisation to allow urgent introduction of an industrial chemical.

As a result of these changes, overall costs to businesses seeking to introduce such chemicals, and to consumers of those chemicals, should be reduced. The capacity for new low-risk industrial chemicals to undergo a simpler regulatory process is also expected to provide greater incentive to introduce greener, safer chemicals. An additional benefit is that these may be able to replace existing higher-risk industrial chemicals.

As the new rules are under consideration, companies that expect to introduce new industrial chemicals may wish to provide comments as and when Nicnas seeks feedback.

Although AICIS begins from 1 July 2020, certain changes are already happening. The Industrial Chemicals (Notification and Assessment) Amendment Act 2019 has amended the 1989 Act to, among other things, amend the definition of 'polymer of low concern' to better align it with international definitions. This will increase the number of polymers that fall within it. Polymers of low concern are now exempt from notification.

Animal testing

Perhaps the most high-profile change to the regulation – so far as the general public is concerned – is in respect of animal testing.

'AICIS will ban the use of animal test data that was obtained on or after 1 July 2020 in applications to introduce new industrial chemicals'

AICIS will ban the use of animal test data that was obtained on, or after, 1 July 2020 in applications to introduce new industrial chemicals. The restriction applies only where that chemical is to be used solely in cosmetics, and does not encompass such chemicals that are to be introduced for more than one end use, where at least one of those end uses is not a cosmetic purpose.

The new provisions mean that manufacturers of cosmetic products and importers seeking to import them into Australia, will need to first assess whether they will contain any new industrial chemicals. If so, data in support of an application may not include animal data. This change reflects a global trend to move away from the use of animal data in cosmetics and towards the greater use of other test methods, such as those developed by the European Union Reference Laboratory for Alternatives to Animal Testing.

AICIS will also be supported by a range of offence provisions, which will include fault based, strict liability and civil penalty provisions. This will allow a proportionate response to contraventions of the Act, taking into account any history of offending and other features of the offence.

Related Articles

- Australia's industrial chemicals bill becomes law
- Australia's 'early regulatory changes' now in force
- Australian NGOs celebrate 'huge win' on animal testing ban

Further Information:

- Industrial Chemicals Bill 2017
- National Industrial Chemicals Notification and Assessment Scheme (Nicnas)
- The Industrial Chemicals (Notification and Assessment) Amendment Act 2019
- Industrial Chemicals (Notification and Assessment) Act 1989

Taiwan to close microbead loophole for synthetic waxes

Some waxes not easily degradable in marine environments

24 April 2019 / Enforcement, Microplastics, Personal care, Plastics, Taiwan

Taiwan's EPA plans to close a major loophole in plastic microbead restrictions for personal care and cosmetics products by expanding them to include solid synthetic wax microbeads.

The widened restrictions came in an advance notice of draft revisions to the 'Restrictions on the Manufacture, Import, and Sale of Personal Care and Cosmetics Products Containing Plastic Microbeads' Regulation, issued by the EPA on 19 April.

The notice expands the definition of prohibited plastic microbeads from solids that are less than 5mm to include "solid synthetic wax microbeads which do not contain natural compounds". The draft revision would ban the manufacture and import of personal care or cosmetics products including the synthetic wax microbeads from 1 September and would prohibit the sale of these products from 1 March 2020.

The EPA said that the existing restrictions, which came into force on 1 July 2018, have helped to reduce microbead use.

But it added that artificial polymers, used as additives by some businesses in adapted formulas, including the waxes, were also not easily degradable in marine environments.

In drafting the changes, the EPA says it has followed the lead set by Sweden to extend restrictions.

Public comments on the notice are open until 18 June.

Dennis Engbarth in Taipei

Related Articles

- Ban on manufacture and import of cosmetics and personal care products containing microbeads
- Sweden advocates developing microplastic restrictions at EU level

Further Information:

- Draft changes (in Chinese)

Commission amends EU POPs Regulation

24 April 2019 / Europe, POPs

The European Commission has amended Annexes IV and V to the Regulation on persistent organic pollutants (POPs).

In Annex IV – the list of substances subject to waste management provisions set out in Article 7 – it has added an entry for pentachlorophenol and its salts and esters with a concentration limit, as referred to in Article 7(4)(a), set at 100mg/kg.

In Annex V on waste management, the Commission has replaced a table with a new one, which lists different types of waste and their maximum concentration limits as itemised in Annex IV, as well as conditions for permanent storage.

The Regulation will enter into force on the twentieth day, following its publication in the EU's *Official Journal*. It will apply from 31 October.

On 18 April, the European Parliament adopted the new limit for the cumulative sum of all BDEs in articles and mixtures under the EU POPs Regulation, set at 500mg/kg. It was adopted as part of the recast of the Regulation after Council of Ministers agreement in February.

Related Articles

- Council of Ministers and Parliament agree on EU POPs update

Further Information:

- Official Journal entry
- POPs Regulation

Canadian draft screening assessment provisionally clears diazenedicarboxamide

24 April 2019 / Canada, Environmental Protection Act, Risk assessment

The Canadian government has provisionally concluded that diazenedicarboxamide does not pose significant risks to human health or the environment at current levels of exposure.

A draft screening assessment published this month proposed to conclude that the substance does not meet any of the criteria of section 64 of the Canadian Environmental Protection Act, 1999 (Cepa).

Diazenedicarboxamide does not occur naturally in the environment. There is no reported manufacturing of the substance in Canada, but up to one million kilograms were imported into the country during one reported year.

It has commercial uses in the food and beverage industry, automotive manufacturing, fabrication of floor coverings, as well as in the manufacture of polyvinyl chloride for building or construction materials.

The substance was determined to exhibit low ecological risk due to its low hazard and low exposure potential. Health effects were observed at high doses in laboratory studies, including on the kidney. However, the expected minimal potential for exposure of the general population led to the conclusion that the potential risk to human health was low.

There is limited information on the concentration of diazenedicarboxamide remaining in products available to consumers. This was identified as an uncertainty during the evaluation of risk to human health.

The ecological portion of the draft assessment was based on the ecological risk classification of organic substances document, which was published in July 2016 and subject to an external review as well as a 60-day public comment period.

Maria Delaney

Reporter

Further Information:

- Draft screening assessment

Echa unveils poison centres submission portal

24 April 2019 / Accidents, emergency response & poison centres, CLP Regulation, Europe

EU companies placing hazardous mixtures on the single market can now make a single submission via a new Echa portal to notify poison centres in several member states.

The information must be provided in accordance with Annex VIII of the classification, labelling and packaging (CLP) Regulation in a harmonised format from the following dates:

- 1 January 2020 for mixtures for consumer use;
- 1 January 2021 for mixtures for professional use; and

- 1 January 2024 for mixtures for industrial use.

The appointed bodies in member states make this information available to poison centres, which can then provide rapid medical advice in the event of an emergency.

The agency says the portal is a secure, online way to centrally manage notifications – creating, submitting and following their status. It will also, the agency adds, reduce administrative burden and costs for companies, when submitting information on hazardous mixtures to appointed bodies in EU member states and EEA countries.

Echa is not charging a fee for the use of the portal, but some member states may levy fees to cover their costs. Notifications submitted through the portal will be valid, once the relevant member state is ready to accept them.

The agency will make further improvements to the user interface and add more functionalities in July and November.

Earlier this year Cefic and other industry associations said they welcomed an interim progress report on workability issues concerning the implementation of Annex VIII of CLP.

Industry has previously aired its concerns that delays and unresolved issues mean it will be "impossible" for the European Commission to deliver the IT tools needed for the 1 January 2020 deadline.

Related Articles

- CLP report examines poison centre mixture provisions issue
- EU CLP poison centres notification deadline 'impossible' to meet

Further Information:

- Submission portal
- Press release

Pregnancy protects against lung inflammation from silica, study suggests

Dampened immune response

24 April 2019 / Global, Nanomaterials, Risk assessment

Pregnant women are generally identified as a susceptible sub-population for the purposes of risk assessment but an Australian study suggests that this may not be the case for all exposures and endpoints.

Pregnancy may in fact protect against the damaging inflammatory effects of silica particles, according to a rodent study at the University of Tasmania, Australia.

The researchers exposed both pregnant and non-pregnant mice to three forms of particulate matter (PM) commonly found in air pollution: diesel exhaust particles, iron oxide and silica. These are all less than 10mm (PM 10) in diameter and are able to bypass the upper airway defences and deposit in the airways.

PM 10 elicit an inflammatory response, which is thought to be linked to the detrimental health outcomes associated with exposure to air pollution.

The researchers found that pregnancy reduced the inflammatory response to silica and altered the immune response to diesel exhaust particles. There was no difference in the immune response to iron oxide.

For both silica and diesel exhaust particles, there was an increase in regulatory T cells in the pregnant mice. Regulatory T cells are involved in shutting down immune responses and have been shown to suppress the inflammatory response to fine PM.

Silica also had an additional effect on immune response. It caused a significant influx of white blood cells into the lungs of both groups of mice, but the researchers found that this response was suppressed in pregnant mice. This means that pregnancy resulted in reduced lung inflammation.

This is consistent with data from pro-inflammatory diseases, such as rheumatoid arthritis, in which inflammation becomes suppressed during pregnancy, resulting in an improvement of symptoms.

The study is published in the journal *Chemosphere*.

Maria Delaney

Reporter

Further Information:

- Journal abstract

Washington state passes 'strongest legislation' on chemicals in products in US

Priority products bill awaits governor's signature to become law

24 April 2019 / Priority substances, US states

Washington's state legislature has passed a bill that would put in place a scheme to identify, and then impose restrictions or prohibitions on, chemicals of concern in products. Its supporters say that if it becomes law, it will be the "nation's strongest policy for regulating toxic chemicals in consumer products".

The Pollution Prevention for Our Future Act (SB 5135) calls for the state's Department of Ecology (DOE) to take action on consumer products containing high-concern chemicals. It identifies as priorities substances like PFASs, phthalates, flame retardants, phenolic compounds and PCBs.

The introduction of the bill came after a taskforce responsible for determining approaches for protecting the area's endangered orca whale population identified toxic contaminants as a priority threat last year.

The Senate narrowly passed the bill last month. An amended version passed the House last week on a 60-37 vote, and the Senate concurred with the updated legislation on 22 April by a 27-22 margin.

The measure now heads to Governor Jay Inslee, who is expected to sign it into law.

Bill details

The measure directs the ecology department to "determine regulatory actions to increase transparency and to reduce the use of priority chemicals in priority consumer products."

This could include notification requirements, such as providing lists of products containing priority chemicals, product ingredient disclosure or information regarding exposure and chemical hazard.

The measure directs the ecology department to 'determine regulatory actions to increase transparency and to reduce the use of priority chemicals in priority consumer products'

But the legislation also authorises the department to restrict or prohibit priority substances when it determines that a safer alternative is "feasible and available", and that such an elimination will "reduce a significant source or use" of a chemical, or if doing so is necessary to protect the health of sensitive populations or species.

The legislation outlines the criteria for identifying priority substances, which include whether they are persistent, bioaccumulative and toxic (PBT) or listed on the state's Chemicals of Concern to Children (CHCC) list.

Substances may also be designated if they are of concern to sensitive populations and species, taking into consideration such factors as their environmental and toxicological endpoints, potential exposures, and potential to degrade, form reaction products or metabolise into other concerning substances.

Priority products are those identified as "a significant source or use" of priority substances. Exempted from the measure are food and beverages, motor vehicles, drugs, products regulated by the Federal Aviation Administration (FAA) or Department of Defense (DOD) and plastic shipping pallets manufactured before 2012.

The ecology department is also blocked from restricting or requiring disclosure for inaccessible electronic components of electronic products.

'Huge win'

A coalition of NGOs issued a joint statement celebrating the bill's passage.

"This huge win keeps Washington state at the forefront of the nation, stopping the use of harmful chemicals in products that pollute our homes, bodies and waters," said Laurie Valeriano, executive director of Toxic-Free Future.

'This huge win keeps Washington state at the forefront of the nation,' said Laurie Valeriano, executive director of Toxic-Free Future

The act, said Clean Production Action's Cheri Peele, will "help move the market toward safer chemicals in products, which reduces business liability."

Liz Hitchcock, acting director of Safer Chemicals, Healthy Families, added: "Other states and the federal government should follow their lead."

But the measure has faced strong opposition from industry groups, which have argued that the state should use its existing authorities rather than adopt a new programme.

"Despite some improvements to the bill before it was passed by the legislature, the American Chemistry Council (ACC) remains concerned with the bill's underlying presumption that the presence of any identified high priority chemical in a consumer product means that the product is potentially harmful," a spokesperson for the trade group told Chemical Watch.

The American Chemistry Council (ACC) 'remains concerned with the bill's underlying presumption that the presence of any identified high priority chemical in a consumer product means that the product is potentially harmful'

The ACC added it was concerned that the legislation gives the DOE authority to determine if a chemical is "functionally necessary" and if an alternative is "feasible and available".

"Just because an alternative is available and could be used does not mean that it is in the best interest of the consumer to use the alternative," it said. "Giving the department the right to determine the necessity of a chemical product opens the door to decisions not being based on the best available science," it added.

The legislation calls for the DOE to identify its first priority products by 1 June 2020. Regulatory actions to address these would need to be determined two years later, with rules in place to implement the regulatory actions by midway through 2023.

This process is set to repeat on a five-year cycle from 2024.

Kelly Franklin

North America editor

Related Articles

- Washington state considers action on priority chemicals in products
- Washington state eyes action on toxics for orca recovery
- Washington state priority products legislation clears Senate
- Washington state requires reporting of 20 additional chemicals in children's products

Further Information:

- Bill text
- SB 5135
- NGO coalition statement

South Korea releases consumer chemical products standards

Comprehensive rules include phase-in safety checks and labelling requirements

24 April 2019 / Biocides, Cleaning products, K-BPR, Labelling, Product authorisation, Product testing, South Korea

South Korea's Ministry of Environment has published standards that outline the requirements for safety checks, labelling and packaging on consumer chemical products under the Consumer Chemical Products and Biocide Safety Management Law (K-BPR).

The comprehensive rules cover:

- products that are subject to safety checks;
- details on how implementation will be phased in;
- the safety standards; and
- the labelling and packaging standards and methods.

Manufacturers or importers are required to use testing organisations to determine whether their consumer chemical products are in compliance with the safety standards. This requirement applies to both in-house and outsourced manufacturers.

Any data on hazardous substances used for risk assessments, must be submitted to the Korea Environmental Industry and Technology Institute (Keiti). This can include data used for existing domestic or overseas approvals.

A number of consumer chemical products that contain substances regarded as a low risk to health or the environment, for example, acidity (pH) modifiers, are excluded.

Several product types are not covered by these rules and are instead overseen by the National Institute of Environmental Research (Nier) under a separate regulation, which governs consumer chemical products that do not have standards attached to them. These are:

- antibacterials/disinfectants for humidifiers; and

- products used for disease prevention, public health and epidemic prevention.

The rules apply to products used in homes, offices and public use facilities such as schools and hospitals. However, those used solely in non-public working spaces, such as factories and auto repair shops, are not included.

Safety checks completed on a 'representative product' can be applied to derivative products where the use and the product's shape are the same – and where there are no changes in the substances to which the safety standard applies.

Products containing substances that are not intentionally added, which are derived unintentionally or are impossible to completely eliminate, are allowed within a range set out in the risk assessment results.

Safety checks

The standards that apply to consumer chemical products relate to:

- chemical substances;
- the containers, packaging or weight; and
- child protective packaging.

The documents that companies must submit to Keiti for safety checks are set out in appendix 7 of the rules.

Phased implementation

The rules will be phased in but will apply immediately to:

- spray type detergents;
- air fresheners and deodorisers; and
- allowed preservatives in sprays.

They apply to these items, manufactured or imported from 1 July:

- disinfectants (air disinfectants or those for toothbrushes/tongue cleaners);
- repellents for winged insects;
- artificial snow spray; and
- soywax candles.

And they apply to these products, manufactured or imported from 1 January 2020:

- disinfectants, repellents and preservative-treated products; and
- preservatives, preservative products and spray type preservatives.

Companies that obtained approval for products under the Pharmaceutical Affairs Act before 12 February this year can use the previous labelling rules, if the products were manufactured or imported before 1 January.

Labelling and packaging

The safety rules on child protective packaging will be enforced for products manufactured or imported from 1 January 2020.

Labelling must be applied to easily visible surfaces and not on the underside of the product, the handles, connecting parts or concave or convex surfaces.

The MoE issued the notification on 12 February.

Sunny Lee

Asia editor

Related Articles

- K-BPR draft rules expand coverage to 'public health' products
- South Korea issues controls on biocides in spray products
- Pharmaceuticals affairs act (2016 revision)

Further Information:

- Safety and labelling standards and designation of chemical consumer products that are subject to safety check (in Korean)

US EPA faces lawsuit over methylene chloride paint remover ban

Groups challenge exclusion of commercial uses from TSCA final rule

24 April 2019 / Solvents, TSCA, United States

The US EPA is being sued over its recent rule banning the use of methylene chloride in consumer paint removal products, on the grounds that commercial uses have been excluded.

Announced on 15 March, the TSCA section 6 rule covers the manufacture, import, processing and distribution of consumer uses of the products.

However, the EPA excluded commercial uses from the rule. Instead, the agency requested comments to inform "a future rulemaking that could establish a training, certification, and limited access programme for methylene chloride for commercial uses".

This deviation from the original proposal was met with criticism from worker advocates and Congressional Democrats.

And on Friday, two petitions were filed in the US Court of Appeals for the Second Circuit in New York, seeking for a court to compel the EPA to protect workers, bystanders and the general public from the substance.

The petitioners are:

- the Natural Resources Defense Council (NRDC);
- Earthjustice;
- the Labor Council for Latin American Advancement (LCLAA);
- Safer Chemicals, Healthy Families (SCHF);
- the Vermont Public Interest Research Group (VPIRG); and
- two mothers whose sons died after using methylene chloride.

In filing the suit, Jonathan Kalmuss-Katz, a staff attorney at Earthjustice, called the exclusion of commercial uses "a craven and illegal giveaway to companies that want to continue to manufacture and sell deadly paint strippers."

"There is no law, science or policy behind the exclusion of workers from EPA's methylene chloride rule," he said.

Liz Hitchcock, director of Safer Chemicals, Healthy Families, added: "It is absolutely unacceptable that EPA has finalised a rule that will not protect the tens of thousands of workers, whose lives and health are in danger as they come in contact with methylene chloride on the job."

Prohibition

The EPA's ban came more than two years after it was initially proposed during the Obama administration. Use of the products, meanwhile, has caused several deaths.

The section 6 rule is based on a 2014 TSCA workplan assessment of methylene chloride that showed it can cause a range of adverse health effects or death in workers and consumers, including harm to the central nervous system, liver and kidney toxicity, and cancer.

Consumer advocacy groups have sued the agency twice previously for its delayed action; while dozens of retailers committed to stop selling the products.

Meanwhile, the EPA named methylene chloride – along with replacement solvent N-methylpyrrolidone (NMP) – among its first ten chemicals subject to risk evaluation under the amended TSCA.

Final risk evaluation on all ten substances are due by the end of this year. If the agency determines that any of these pose an unreasonable risk, it is required to immediately begin a rulemaking process to address the identified concern.

Nick Hazlewood

News editor

Related Articles

- US EPA bans methylene chloride in consumer paint removers
- US EPA seeks comments on workplace programme for methylene chloride
- US EPA proposes prohibitions on methylene chloride, NMP
- Congressional Democrats criticise methylene chloride rule as 'inadequate'
- US EPA commits to act on methylene chloride paint strippers
- US EPA identifies cancer risks with DCM paint strippers
- US EPA sued over delay to methylene chloride paint stripper restriction
- US DIY firm to stop distributing methylene chloride, NMP paint strippers
- EPA names first ten chemicals for new TSCA evaluations

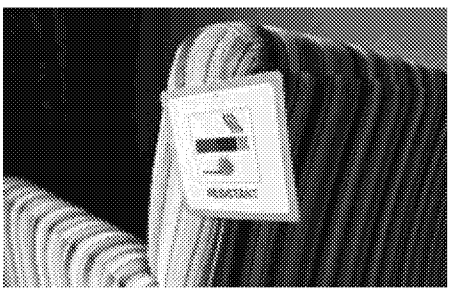
Further Information:

- Earthjustice statement
- NRDC statement
- Petition for Review

NGOs battle EU Commission over POPs flame retardants definition

Argument over 'meaningful use' ahead of UN Conference of the Parties

24 April 2019 / Europe, POPs



A group of NGOs is applying pressure on the European Commission to withdraw its registration for the recycling of polybrominated diphenyl ether (PBDE) flame retardants, at the 9th Conference of the Parties of the Stockholm Convention.

The new limit for the cumulative sum of all BDEs – which includes decaBDE – in articles and mixtures under the EU POPs Regulation is set at 500mg/kg. It was adopted on 18 April by the European Parliament as part of the recast of the Regulation after Council agreement in February.

In an exchange of letters ahead of the COP, which will take place from 29 April to 10 May, the seven NGOs disputed EU environment commissioner Karmenu Vella's argument that the limit value is within that specified as the unintentional trace contaminant level, in accordance with Article 4(1)(b) of the recast.

The definition of unintentional trace contamination, the NGOs said, is "a level below which the substance cannot be meaningfully used and above the detection limit of existing detection methods to enable control and enforcement".

The group, which includes Arnika, the Centre for International Envirionmental Law (Ciel), the European Environmental Bureau (EEB), the Health and Environment Alliance (HEAL) and the International POPs Elimination Network (Ipen), argued that the 500mg/kg (ppm) concentration value of PBDEs "certainly does not constitute a 'meaningful use' as it cannot supply a flame retardant function".

Conventional laboratory methods, such as gas chromatography coupled with mass spectrometry, can measure PBDEs with a 0.5-2.5ng/g (ppb) limit of detection, they said. "For this reason, the current value of 500mg/kg (ppm) does not meet the definition of unintentional trace contamination."

There is no reason, they add, to increase the limit value above 10ppm for unintentional trace contaminants.

The levels of PBDEs measured in recycled plastic products on the EU market are "too high to be consistent with unintentional trace contaminants", the group said. Data indicates that the levels in these products are the result of toxic recycling, they said.

The levels of PBDEs measured in recycled plastic products on the EU market are too high to be consistent with unintentional trace contaminants, say the NGOs

This "directly conflicts" with the convention's prohibition on the recycling of materials containing decaBDE.

"If the European Commission insists that only unintentional trace contamination of PBDEs in articles is allowed, then the European Union should publicly withdraw its registration for the recycling of PBDEs [...] at the upcoming 9th Conference of the Parties of the Stockholm Convention."

The "principal consequence" of the PBDE recycling exemption in the Stockholm Convention, the group said, is contamination of products made of recycled plastic or foam with toxic chemicals.

To comply with the convention, the sum limit for tetra-, penta-, hexa-, hepta, and decaBDE should be 10ppm for decaBDE and other PBDE substances, giving the alternative of a maximum of 50ppm for the sum of all POP-PBDEs, the NGOs added.

Waste limit

In its letter, the group also raised concerns about the 1,000mg/kg waste limit.

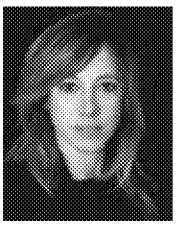
They argued that the original concentration limit of 1,000mg/kg (ppm) for the sum of the POP-PBDEs (tetra-, penta-, hexa-, heptaBDE) in waste, established in Annex IV of the recast, was "set inconsistently" with the conclusions of the EU's own consultants.

The recommended lower level for each of the PBDEs (tetra-, penta-, hexa- and heptaBDE) was 10ppm. This, the NGOs said, meant a total of 50ppm for mixtures of the POP-BDEs including decaBDE – not 1,000mg/kg.

The proposed limit of 1,000ppm for PBDEs "should be strengthened to a science-based limitation of 50ppm".

While the policies have a revision clause after two years, the data on PBDE contamination in EU consumer products "should result in a prompt revision to prevent further contamination and exposure", they added.

EU consumers should be able to purchase products made of recycled materials "without having to worry that they contain substances that are globally banned due to their very harmful properties".



Caterina Tani

Europe reporter

Related Articles

- EU flame retardants threshold still too high, say NGOs
- Council of Ministers and Parliament agree on EU POPs update

Further Information:

- NGO letter
- Parliament recast
- NGO report

EU report proposes screening criteria for POPs to capture mobility

Close to 1,000 substances could meet criteria

24 April 2019 / CLP Regulation, PBT/vPvB, POPs, REACH

A report commissioned by the EU has proposed new screening criteria to identify potential persistent organic pollutants (POPs) on the basis of their mobility in the environment.

If adopted, the criteria would identify perfluorinated compounds pentadecafluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), used as surfactants, as POPs under the Stockholm Convention.

The report by consultancy Peter Fisk Associates was circulated at the meeting of the Competent Authorities for REACH and CLP (Caracal) on 19-20 March.

It suggests that the criteria are included in Annex D of the convention for bioaccumulation. They could be considered under criterion c(ii), which calls for evidence that a chemical presents "other reasons for concerns, such as high bioaccumulation in other species, high toxicity or ecotoxicity".

Mobility is an emerging issue that could impact human health and the environment in the future.

In January, the EU's Scientific Committee on Health, Environmental and Emerging Risks (Scheer) identified persistent, mobile and toxic substances (PMTs) as one of 14 emerging issues. It will use this when discussing potential mandates from the Commission.

Germany's Federal Environment Agency (UBA) developed the PMT concept and suggested that PMTs could be identified as substances of very high concern (SVHCs) under REACH.

The aim of the UBA proposal is to protect humans and the environment from substances that have the potential to circulate very widely in water systems and contaminate, in particular, drinking water. Industry is opposed to it, warning of a rush to 'regrettable' regulation.

The Peter Fisk report authors searched the OECD's eChemPortal and came up with 970 substances that would meet UBA's mobility criteria. There were 830 others considered as 'very mobile'.

The study investigated whether the mobility concerns related to drinking water can be extended to bioaccumulation-based concerns outlined in Annex D.

Its report concludes that a wider range of criteria is necessary to capture mobility of substances that have lower bioconcentration/bioaccumulation factors, but which may accumulate over longer time periods.

This includes consideration of how the substances are transported, for example, via water, air or a combination of both, and persistence over longer time-scales than currently included in Stockholm, it says.

Body burden

According to the report, the current POPs criteria are appropriate for substances that reach relatively high 'body burdens' over short time periods.

But substances that are both persistent and mobile have the potential to be transported long distances from the point of emission, the report says. If they accumulate over time in remote regions, "they can reach levels that may have effects on both ecosystems and human health".

Examples include PFOA and PFOS. These persist for very long periods in the environment and are capable of being transported and distributed globally, but the current screening for bioaccumulation would not necessarily identify them against the standard Annex D criteria, the report says.

For such substances, it suggests a half-life in water, sediment or soil of greater than one year. For some substances with relatively long degradation half-lives in air (50 days or more), a shorter half-life of 180 days in water or soil may be more appropriate, it adds.

The proposed criteria have been validated using substances that do not meet the current Stockholm Convention criteria for bioaccumulation, but which have been agreed to be POPs, the report notes.

However, it adds, the criteria should be seen as the starting point for identifying potential candidates for further evaluation and suggests "a proper assessment on a case-by-case basis".

The Norwegian Geotechnical Institute (NGI) last year compiled a list of 240 REACH-registered substances that potentially fulfil the proposed PMT and very persistent, very mobile (vPvM) criteria or are candidate substances.

And last month, the Netherlands proposed HFPO-DA, also known as GenX, as an SVHC on the basis of its environmental mobility – the first time the concern has been considered as a distinct property.

Clelia Oziel

Europe correspondent

Related Articles

- EU committee lists persistent mobile substances as emerging issue
- 'Mobile' substances in water could be SVHCs, Germany says
- Cefic says SVHC equivalency must be judged 'case-by-case'
- Dutch SVHC action against GenX is 'first of kind'

Further Information:

- Report

US FDA to survey cosmetics manufacturers

25 April 2019 / Personal care, United States

The US Food and Drug Administration (FDA) has announced plans to conduct a survey of manufacturing processes used in the cosmetics industry, with a particular focus on the practices companies use to ensure product quality and safety.

The FDA says it comes as part of its "ongoing effort to add to our understanding of the cosmetic industry and manufacturing practices."

"To date, the FDA has not identified in the published literature any systematic, detailed study that could enlighten the FDA on the diversity of practices and standards employed across the cosmetic industry," it said. The survey is intended to fill this knowledge gap.

The agency says it has randomly selected around 900 manufacturers to take part. An outside contractor will be reporting only "unidentified individual responses" to the FDA, and masking information so that responders cannot be identified.

Once complete, the results will be shared with the public.

Further Information:

- Notice
- 20 December 2018 proposal

CPSC considers changes to US clothing textiles flammability standard

25 April 2019 / Solvents, Textiles & apparel, United States

The US Consumer Product Safety Commission (CPSC) is seeking feedback on possible changes to its flammability standard for clothing textiles.

Among the proposed amendments is one expanding the list of fabrics that are exempt from testing under the standard to include spandex.

The agency is also taking comment on a dry cleaning procedure specified as part of the process for refurbishing plain and raised textile fabrics. The existing procedure calls for the solvent perchloroethylene.

"Staff is aware of the limited availability of, and legal restrictions on the use of, perchloroethylene solvent," says the 23 April *Federal Register* notice. Perchloroethylene is one of the first ten substances subject to risk evaluation under the reformed TSCA.

The CPSC is seeking comment on the testing burden and cost of performing this dry cleaning procedure, and has asked for information on potential alternatives.

General recommendations for how the agency can reduce the cost of testing requirements associated with it flammability standard for clothing textiles are also being accepted.

Comments are due 24 June.

Related Articles

- EPA names first ten chemicals for new TSCA evaluations

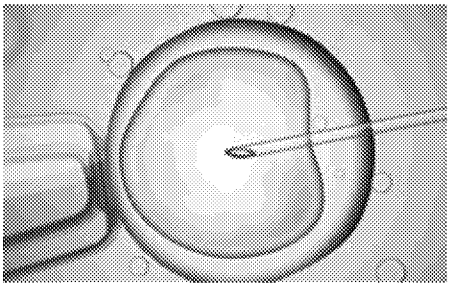
Further Information:

- Federal Register notice

Saudi study links phthalate exposure in couples to failed pregnancy

Importance of couple-based assessment approach

25 April 2019 / Phthalates, Saudi Arabia



A study of almost 600 couples in an IVF clinic in Saudi Arabia has found an apparent association between phthalate exposure and an increased risk of failed clinical pregnancy and live birth.

The association was stronger when phthalate levels in both women and their male partners were taken into account, illustrating the importance of following a couple-based approach for assessing fertility outcomes.

Phthalates are used as plasticisers in polyvinyl chloride products and are present in everyday products such as cosmetics, food, toys and construction materials.

The researchers looked at the exposure levels of both men and women, undergoing either *in vitro* fertilisation (IVF) or intracytoplasmic sperm injection (ICSI) in the King Faisal Specialist Hospital and Research Centre in Riyadh.

They measured eight known metabolites in urine:

- monoethyl phthalate (MEP);
- mono-n-butyl phthalate (MnBP);
- mono-iso-butyl phthalate (MiBP);
- monobenzyl phthalate (MBzP);
- mono-(2-ethylhexyl) phthalate (MEHP);
- mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP);
- mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP); and
- mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP)

Their analysis reveals high phthalate exposure among the couples undergoing fertility treatment.

"Parental high exposure to phthalates should be of great public health concern due to their developmental and reproductive effects, so more research is needed," they write in the journal *Chemosphere*.

In particular, MEP and MEHP were associated with the biggest increase in risk of failed clinical pregnancy and live birth.

MEHP was also associated with the risk of a biochemical pregnancy, which is a very early miscarriage that occurs in the first few days of pregnancy. In line with previous research, they found no association between a reduced fertilisation rate and urinary phthalate metabolites in women or men in this study.

Since critical events in human reproduction are difficult to observe in women conceiving naturally, IVF provides an opportunity to acquire evidence of the impact of environmental pollutants.

The researchers point to the study's limitations and recommend that the results should be "interpreted with caution". Nevertheless, they say that their findings "support the current evidence that exposure of couples to phthalates can influence IVF outcome".

The results should spark "concern" because of the "broader impact of these chemicals on other health outcomes", they conclude.

Maria Delaney

Reporter

Further Information:

- Chemosphere

Post-Brexit skills shortage could hamper UK chemicals agency

Experts share views at Environmental Audit Committee inquiry

25 April 2019 / Brexit, REACH, UK

The UK would "struggle tremendously" to set up its own chemicals agency post-Brexit because of a severe skills shortage, according to four leading toxicology experts speaking at the first session of the UK Environmental Audit Committee's inquiry into toxic chemicals in everyday life.

"There has been a tremendous lack of funding over many years from the research councils for training students in ecotoxicology, toxicology and environmental chemistry," said Michael Depledge from the University of Exeter's Medical School.

The scientists – all of whom are on Defra's Hazardous Substances Advisory Committee (HSAC) – strongly advised that the UK should continue to follow EU chemical regulations, because the UK does not have the expertise to replace them. "Sticking with the EU would be by far the wisest thing that we could do," said John Sumpter from Brunel University London.

Andrew Johnson from research organisation the Centre for Ecology and Hydrology warned that "it would be alarming to lose a lot of the collaboration and expertise and benefits that we get from Echa, should we be put in that position". But, he added, it would be valuable for the UK to be able to review its approach to chemical regulation. "We shouldn't be afraid of getting the best knowledge and expertise from around the world, learning from that previous experience."

Chair Mary Creagh MP voiced the committee's concerns over the UK's plans post-Brexit. "In terms of the HSE [Health and Safety Executive], which would be the new chemicals regulator, we, this committee, was concerned that there would be a number of management and technical committees that would not be replicated in the way that they are under REACH. And no accredited stakeholders, NGOs and trade unions being able to attend," she said.

"The Commission's role is taken over by the Secretary of State, so it's officials advising minister and then it's ministerial fiat essentially regulating chemicals," she warned.

Chemical numbers

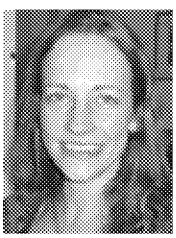
The experts are alarmed by the rate at which new chemicals appear on the market. As members of HSAC, "one of the things that has emerged from our discussions is the fact that since 1950 there has been a 50-fold increase in global chemical production. And by 2050 we think there will be another three-fold increase, which is huge," said Professor Depledge.

"One of the challenges is to try to define a chemical environment that we would find acceptable to live in. And once we have done that we need to develop policies that would take us to that place," he added. "At the moment it is firefighting. Each chemical that comes along – probably there are about 2,000 new chemicals a year coming along – we try to make regulations for them. We can't get through them all."

Professor Sumpter called for a move away from today's testing of an endless stream of single chemicals. "The only sensible strategy probably is to say we need to be using [fewer] chemicals. And that is probably the only way to drive down exposure ... We are going in the opposite direction at the moment," he said.

The experts agreed that public education is critical. "We have made a really rather poor job of making people aware of what chemicals they are exposed to, what the risks are, how they can minimise those risks and so on. Most people are not aware of what they are exposed to," said Professor Depledge.

The Environmental Audit Committee started its inquiry in February. It is focusing on how toxic chemicals are used in everyday substances, on environmental and human health problems, and on current government regulation.



Dr Emma Davies

Reporter

Related Articles

- UK audit committee launches inquiry into toxic chemicals

Further Information:

- Inquiry
- Meeting recording

Sweden finds chemicals leaking from squeezable plastic toys

25 April 2019 / Children's products, Enforcement, Substances of concern, Toy safety Directive

Tests conducted in Sweden on squeezable or 'squishy' soft plastic toys have found that they leaked chemicals that can cause irritation to the eyes and the respiratory tract.

The Swedish Chemicals Agency (Kemi) said all of the 21 squishy toys it tested leaked irritant substances, with the highest concentrations occurring when the toy is first removed from the package. The leakage decreased over time, it added.

The results follow the European Commission's latest report on the EU's Safety Gate rapid alert system for dangerous products (Rapex), which identified squishy toys as an emerging area of concern.

There were 23 alerts in 2018 for these types of toys, 14 of them due to a chemical-related risk.

Kemi tested the toys, made from foamed polyurethane plastic, for seven types of chemicals. These were:

- dimetylaminoetanol;
- N,N-dimetylformamid (DMF);
- cyklohexanon;
- trietylendiamin;
- bis(2-(dimetylamino)etyl)eter);
- 1,1,4,7,7-pentametyldietylentriamin; and
- xylen.

It concluded that the risks the squishy toys may pose to children are not compatible with the EU legislation on toy safety and should be removed from the market.

Kemi's tests followed similar findings in a survey last year by the Danish EPA.

Children should avoid playing with squishy toys close to the face, for example by squeezing or smelling them, and should not sleep with them, the agency said. They should not be given to babies and toddlers as they may bite or suck them and this can cause suffocation, it added.

It has also asked manufacturers to investigate the presence of harmful substances and determine whether they may pose a risk to children. Other products made of the same material should also be examined, Kemi said.

The agency called for a review of how the risk from the substances found in foamed polyurethane can be regulated in the toy safety legislation.

Related Articles

- Chemicals top EU notifications for product risk
- Denmark to tighten rules on toy safety

Further Information:

- Report (in Swedish)
- Press release

Enforcement authorities not equipped for possible REACH authorisation review

Concern over draft Implementing Regulation on companies increasing volumes of usage

25 April 2019 / Alternatives assessment & substitution, Enforcement, Europe, REACH

European national enforcement authorities (NEAs) will be unable to execute new duties under a Commission proposal concerning companies that, once granted an authorisation to use an SVHC, increase volumes of usage.

Spain's ministry of health and the Norwegian environment agency made the point in separate papers, submitted after the meeting of the Competent Authorities for REACH and CLP (Caracal) on 19-20 March.

A European Commission document submitted prior to the meeting said that such companies may need to apply for a review of their authorisation decisions. This would take the form of a draft Implementing Regulation.

Changes in volumes may be accompanied by changes in risk management measures and operational conditions in order to limit exposure, Spain said.

The Commission's document proposes that these changes be documented by the authorisation holder and verified by NEAs.

'In our opinion, changes in any element that has been considered for the exposure assessment, and during the process of development of an opinion, could challenge the conditions established in the decision'

The task of NEAs is to check whether the authorisation holder complies with conditions established in the authorisation decision.

"In our opinion, changes in any element that has been considered for the exposure assessment, and during the process of development of an opinion, could challenge the conditions established in the decision," Spain said.

Therefore, it added, there is "always a need for a reevaluation process of these conditions", but this does not fall within the obligations for NEAs.

"This reevaluation process can't be executed by NEAs – not only due to competence reasons, but also because they do not have neither the knowledge nor the resources to assess the exposure and the corresponding risk under other different conditions that those assessed by Rac [Echa's Risk Assessment Committee]."

Instead, Spain suggested that Echa is in the position to ascertain "if a change in one or several elements considered in their evaluation will have an impact on the appropriateness and effectiveness of the conditions set in the authorisation and they can conclude if the conditions are still valid."

German stance

In a separate paper to the Caracal, Germany's Federal Institute for Occupational Safety and Health (Baua) said it agrees a clear and suitable solution is needed, based on REACH provisions.

If an authorisation holder implements changes in the use of the substance, the basis for the authorisation decision is considered to be no longer valid. Legal provisions for such changes are "clearly defined" in REACH, especially in Article 61, and therefore have to be applied for in such cases, it added.

The described changes in the use conditions create a new situation, which requires a new application including a detailed description of all relevant changes, Baua said.

"The new application should allow Echa – but also Commission at a later stage – to reevaluate all relevant parameters, but especially the exposure and the corresponding risk."

NGO comment

In a paper, also submitted after the Caracal meeting, the European Environmental Bureau raised concerns that one of the applicants mentioned in the Commission document has already implemented the change.

At this stage, the EEB said: "There is no guarantee whatsoever that those unilaterally operated change(s) meet the conditions to ensure their legality."

One of the options provided in REACH is that the Commission may withdraw the authorisation, taking into account the principle of proportionality, in line with Article 61.3, it said. Pending this review, the Commission may also suspend the authorisation.

"The EEB also regrets the lack of transparency of this process as the document does not specify any tonnage band reference, any substance name or any use of those SVHCs. Instead, the document frames the issue in a generic manner although such information should impact the decision-making process."

Luke Buxton

Europe editor

Related Articles

- Commission considers implementing Regulation on REACH authorisation

Further Information:

- Commission document
- Spain paper
- Norway paper
- Germany paper
- EEB comments

US EPA round-up

25 April 2019 / TSCA, United States

TSCA proposals, asbestos Snur formally published

The US EPA has published in the *Federal Register*:

- a proposed rule to establish a plan for how the agency will require substantiation for, and review the validity of, claims to withhold the identity of a substance as confidential, initially announced on 10 April;
- proposed revisions to the TSCA chemical data reporting (CDR) rule and update to the small business definition for reporting purposes, first announced on 12 April; and
- a final TSCA significant new use rule (Snur) for asbestos, originally announced on 17 April.

Comments on both the confidential business information (CBI) proposal and the CDR revisions will be accepted until 24 June. The asbestos Snur takes effect on the same day.

EPA prints correction to PV29 notice

The US EPA has issued a correction to its 17 April *Federal Register* notice that reopened the comment period for its risk evaluation of pigment violet 29.

The agency clarified that the comment deadline, advised as 17 April, should read 17 May.

TSCA PBT risk management proposal heads to interagency review

The agency has submitted a proposed regulation for five persistent, bioaccumulative and toxic (PBT) substances to the White House's Office of Management and Budget (OMB) for review and approval.

Under the reformed TSCA, the EPA must take 'expedited' action on PBTs meeting certain criteria. For these, it will skip their risk evaluation and proceed directly to a risk management rule to reduce their exposure "to the extent practicable".

Announced in October 2016, the five substances that met the PBT definition are:

- decaBDE;
- hexachlorobutadiene (HCBD);
- pentachlorothiophenol (PCTP);
- tris(4-isopropylphenyl) phosphate (IPTPP); and
- 2,4,6-tris(tert-butyl) phenol.

The proposed rule was received at OMB on 24 April. The EPA is required to issue the proposal by 22 June, with a final version due 18 months later.

Related Articles

- US EPA issues proposal for CBI substantiation
- US EPA proposes amendments to CDR rule
- US EPA issues final Snur for asbestos
- Comment period reopened for TSCA PV29 evaluation
- Academics, NGOs protest TSCA PBT risk review approach
- EPA names TSCA fast-tracked PBTs

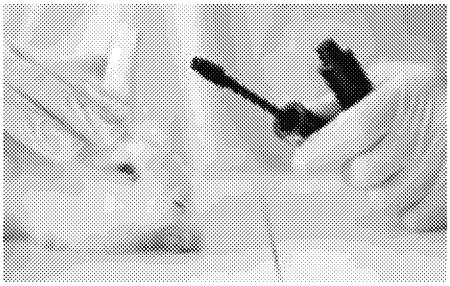
Further Information:

- CBI proposal
- CDR proposal
- Asbestos Snur
- PV29 notice
- PBT OMB review

Canada considers ban on animal testing for cosmetics

Measure passed Senate unanimously, but faces time-crunch in House

25 April 2019 / Alternative approaches to testing, Canada, Product testing



A bill to ban the sale and manufacture of cosmetics tested on animals has been introduced into Canada's House of Commons after its unanimous passage in the Senate last year.

However, the Commons will only have until the federal elections in October to pass the bill (S-214). This short timeline is proving the main concern for its advocates.

"There's a real indication that there's lots of potential for it to pass," Liz White, director of Animal Alliance Canada, told Chemical Watch. "I think the difficulty is that we're in a very tight timeframe. And so at committee, if there's something that somebody suggests that makes it more difficult for us to support or ... for the industry to support, it makes it more difficult to get the bill passed."

S-214 would amend Canada's Food and Drug Act to ban the sale and manufacture of cosmetics tested on animals, or containing any ingredients tested on animals. It also stipulates that "no evidence derived from animal testing" and conducted more than four years after the bill comes into force may be used to establish the safety of a product or ingredient.

The ban will not apply to animal testing authorised by the Minister of Health "when there is no alternative method to evaluate substantiated specific human health problems associated with a cosmetic or ingredient", when that product is in wide use and not replaceable with another product "capable of performing a similar function".

The bill was initially introduced in June 2015, but it died with the dissolution of the 41st Parliament. It was reintroduced in December 2015, and passed the Senate in June 2018.

Conservative MP Marilyn Gladu introduced it to the House of Commons on 12 April. The Canadian Cosmetics Alliance worked with Ms Gladu's office as well as other stakeholders to satisfy industry, regulators and both the animal and consumer advocacy communities.

"It is critical for industry that animal testing legislation in Canada align with other jurisdictions – most notably the European Union which is the basis for similar legislation around the world," the Cosmetics Alliance explained in a statement

However, Ms Gladu and Health Minister Ginette Petipas Taylor have apparently acknowledged some problems with the current wording of the bill, and plan to work together on certain changes. Cosmetics Alliance Canada outlined several of these, including:

- ignoring the practical reality that certain cosmetic ingredients are used in products such as drugs or consumer products, which are outside the scope of this bill;
- not clarifying who is legally responsible for complying with the bill (and includes retailers, who are not responsible "manufacturers" as defined in the Cosmetics Regulations); and
- limiting Health Canada's discretion to allow testing to protect human health and safety, as well as the Minister's ability to exempt a new substance for use in cosmetics, even if it is a safer alternative.

Animal Alliance Canada and Humane Society International/Canada both also contributed their input to the current version of the bill. Ms White said they are encouraged by the "broad support" the bill has seen so far, and believe that even if the bill dies at the end of this legislative session, it is "a good working document" to reintroduce in short order.

"I think a lot of the companies just want to get this issue dealt with," she continued.

If the ban is ultimately passed, Canada will join the EU, Australia and Turkey, among others, in banning the sale of cosmetics tested on animals.

Lisa Martine Jenkins

Americas reporter

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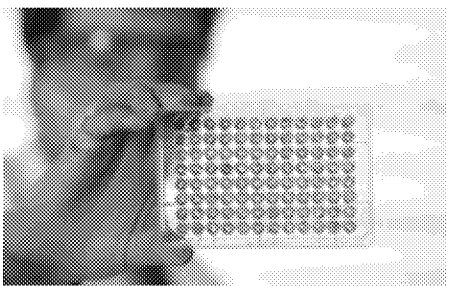
Further Information:

- Bill text
- Cosmetics Alliance Canada statement

Rutgers team predicts toxicity by mining PubChem data

Starting with acute oral toxicity

25 April 2019 / Software, United States



A US team has created an algorithm to predict the toxicity of unknown chemicals by mining bioassay data held in a US National Institutes of Health database.

Many studies use computers to compare untested chemicals with structurally similar compounds whose toxicity is already known. But the results can be confounded by the fact that structurally similar chemicals may have very different levels of toxicity.

The new method uses fragments of chemical structures and biological information from *in vitro* tests. The approach not only predicts acute oral toxicity classification, but also hints at biological mechanisms, the researchers suggest.

A team led by Hao Zhu from Rutgers University, and including Thomas Hartung from Johns Hopkins Bloomberg School of Public Health, first built a training database of more than 7,000 compounds with associated rat acute oral toxicity data. They then created "bioprofiles" for the chemicals based on *in vitro* data in PubChem, a public database that is updated daily.

Using a new "clustering" algorithm, they picked out groups of bioassays that are likely to provide information on toxicity mechanisms underlying acute oral toxicity. The researchers then attempted to predict the animal acute oral toxicity of new chemicals using read-across, based on bioassay clusters.

They tested their system with 600 new compounds. Several bioassay clusters showed "high predictivity" for acute oral toxicity, they say.

The bioassay cluster-based models and another that combines cluster predictions "show great promise" for predicting acute oral toxicity, as well as informing on possible mechanisms contributing to toxicity, the researchers add.

Writing in *Environmental Health Perspectives*, they say that their method could "easily be expanded" to evaluate other animal toxicities beyond acute oral systemic toxicity.

Professor Hartung is one of the architects of a widely publicised computational tool for predicting chemical toxicity, commercialised by safety science company Underwriters Laboratories (UL).

Dr Emma Davies

Reporter

Related Articles

- Machine learning and big data may outperform animals, study suggests

Further Information:

- Journal article (open access)

Massachusetts notifies expansions to reportable substances list

25 April 2019 / Halocarbons, US states

Massachusetts's Department of Environmental Protection has provided guidance on recent additions to its list of reportable substances under the state's Toxics Use Reduction Act (Tura).

A 3 April notice outlines changes to the reporting scheme, which requires users of large quantities of certain toxic substances to report annually and pay a fee.

Among these is a requirement to begin reporting next year for C1-C4 halogenated hydrocarbons and halocarbons. These are defined as "chemicals with four or fewer carbons, at least one halogen, and only hydrogen as the other constituent, that are not already individually listed on the Tura chemical list."

Effective in reporting year 2020, the state will also require reporting for a nonylphenol ethoxylates (NPEs) category.

MassDEP notes that, although these reports will not be due until 2020 or 2021, it is important that companies begin tracking the substances' use now.

The notice also clarifies that for the current reporting year, reports must be submitted for the hexabromocyclododecane (HBCD) category. Reports covering 2018 activities are due on 1 July.

Under Tura, facilities that manufacture, process or use a regulated chemical above certain reporting thresholds are generally required to report to the state. The state's list of reportable substances includes those on the US EPA's Toxics Release Inventory (TRI) list and the Comprehensive Environmental Response, Compensation, and Liability Act (Cercla) 'Superfund' list.

Kelly Franklin

North America editor

Further Information:

- 3 April notice
- Toxics Use Reduction programme

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